DEVICE FOR RADIAL OPTIC NEUROTOMY

This application claims priority of Provisional Patent Application #60/397,793, filed 7/24/2002.

BACKGROUND OF THE INVENTION

The art of the present invention relates to eye surgical devices in general and more particularly to an improved and modified form of a microvitreoretinal (MVR) blade having elements and features especially suited for radial optic neurotomy (RON) as a treatment for central retinal vein occlusion (CRVO).

Central retinal vein occlusion (CRVO) is a relatively common condition, reported to occur in approximately 60,000 new patients each year within the United States. Its etiology is poorly understood, with a wide array of medical and systemic disorders debated as to their potential causative effect. CRVO is most commonly reported in patients aged 50 to 80 years, with a statistical tendency towards those patients suffering from hypertension and/or glaucoma. The natural history of this condition can result in loss of vision due to extensive intraretinal hemorrhage, macular edema, iris neovascularization, neovascular glaucoma, and ischemic retinal infarct. Spontaneous resolution is uncommon; rather, it is most widely reported to have catastrophic consequences to affected patients.

There is no effective curative therapy for CRVO. Panretinal photocoagulation can be effective in controlling neovascularization, while grid photocoagulation has been reported to be successful in resolving edema. However, neither therapy restores vision nor reverses the basic occlusive condition. Attempts to create a physiological shunt by way of a of high powered photocoagulating chorioretinal anastomosis has reported some success, but is similarly associated with a high rate of complications. Many theorize that the CRVO is associated with thrombus within the central retinal vein. As such, many developing therapies have concentrated on resolving the thrombus by means of cannulation of the central retinal vein and administration of "clot busting" agents (t-PA). While technically feasible, the clinical results and reproducibility of this procedure remain non-validated.

An emerging hypothesis suggests that CRVO is a vascular complication secondary to a compartment syndrome. This condition is created as the optic nerve enters the eye, experiencing a

reduction in outer diameter from 3.0mm to 1.5mm at the optic nerve head. It is theorized that congenital anatomical variances, connective tissue, persistent myelin sheaths, ocular motion, and other factors may increase pressure within the scleral outlet compartment, thereby resulting in CRVO.

A new surgical procedure, radial optic neurotomy, (RON) addresses this causative factor and, in so doing, potentially provides a curative effect. By inserting a knife radial to the optic nerve head and advancing a specified distance, the compartment syndrome may be relieved by relaxing the cribiform plate, scleral ring, and adjacent sclera. Unfortunately, the greatest potential complication of such a maneuver is hemorrhage. To address this complication, the present art device incorporates design elements and features which minimize this threat.

The present art device is best described as a radial optic neurotomy (RON) knife. The device comprises in its most basic form, a modified conventional microvitreoretinal (MVR) blade with a single sharp nasal portion edge rather than the two opposing sharp edges, both nasally and medially as found in conventional MVR blades. Prior art conventional microvitreoretinal (MVR) knives or blades introduce a significant risk during the RON procedure as the sharp nasal and medial edges may cause an inadvertent disruption or cutting of the central retinal vessels. The single sharp edge of the present art device allows for a radial incision of the optic nerve head, with the incision proceeding nasally. In the present art device, the medial edge, i.e. the edge opposite the single sharp edge, of the blade is specially dulled, thereby allowing atraumatic passage of the knife alongside the central retinal artery and central retinal vein. The present art device further provides a depth gauge or measuring technique via the inclusion of a mark at a desired penetration depth distance from the device tip. Prior art conventional microvitreoretinal (MVR) knives or blades are unmarked, thereby leaving the surgeon without indication as to the actual depth of penetration. This mark provides the surgeon with a specific reference as to the depth of the radial incision, thereby minimizing the potential for globe perforation.

Accordingly, it is an object of the present invention to provide a device for radial optic neurotomy having a sharp edge and a medial dulled edge which is capable of atraumatic passage alongside the central retinal artery and central retinal vein.

Another object of the present invention is to provide a device for radial optic neurotomy having a depth gauge or measuring technique to optimize a desired penetration depth.

SUMMARY OF THE INVENTION

To accomplish the foregoing and other objects of this invention there is provided a device for radial optic neurotomy. The apparatus is especially suited for use with and during the radial optic neurotomy procedure.

The present art device or RON blade first comprises a substantially asymmetrical "V" shaped tip having a distal point, the base or point of said "V" substantially representing the distal end of the present device. In the preferred embodiment, the top or broad portion of said "V" shaped tip is attached with a tip holding shaft having a proximally attached handle. Said asymmetrical "V" shaped tip comprises a first leg of said "V" having the single sharp edge and a second leg of said "V" opposite said first leg comprising a burnished, dulled, or rounded edge.

The preferred embodiment further places a laser mark onto both broad sides of said "V" shaped tip transitional taper area to function as a depth gauge. Again in the preferred embodiment, said laser mark is in the form of a line which is substantially perpendicular with the central shaft axis. Alternative embodiments may place one or more of said marks at any location which would indicate the proper depth of penetration during surgical use or place multiple marks to accommodate varying pathology and/or surgical nuances. Alternative embodiments may further utilize said mark as a partial line or other mark form which is scribed or marked in a fashion other than laser marking or which is positioned in a fashion which is not perpendicular with the central shaft axis or which is located onto only one side.

As aforesaid, a handle or grip attaches with said central shaft opposite said "V" shaped tip and proximal to the user. Preferably said handle or grip is cylindrical in form, but may take many forms or shapes which allow a surgeon to easily utilize the device. The present art device is claimed as the tip in conjunction with the attached shaft and as a further embodiment, the tip with attached shaft and handle or grip.

The "V" shaped tip of the present device may be manufactured from a plurality of materials, these include but are not limited to stainless steel, diamond, both natural and/or synthetic, ruby, obsidian, ceramic, or nickel-titanium alloys. In the preferred embodiment, the shaft is manufactured from stainless steel and the handle or grip is manufactured from a durable high temperature polymer

capable of withstanding autoclave temperatures. The shaft and handle may further be manufactured from any material which is biologically safe for surgical use and further provides the lateral and torsional strength required for surgical use. Further embodiments may also utilize an anti-reflective surface treatment, coating, or process on the tip or shaft.

BRIEF DESCRIPTION OF THE DRAWINGS

Numerous other objects, features and advantages of the invention should now become apparent upon a reading of the following detailed description taken in conjunction with the accompanying drawings, in which:

Fig. 1 is a top plan view of a preferred embodiment of the device for radial optic neurotomy showing the substantially "V" shaped tip with laser mark and tip holding shaft.

Fig. 2 is a left side plan view thereof, which is symmetrical with a right side plan view, of the device for radial optic neurotomy showing the substantially "V" shaped tip with laser mark and tip holding shaft.

Fig. 3 is a cross sectional view thereof taken along line 3-3 in Figure 2.

Fig. 4 is a rear side plan view thereof without attached handle or grip.

Fig. 5 is a left side perspective view thereof of a preferred embodiment fully showing the substantially "V" shaped tip with laser mark, tip holding shaft, and handle or grip, all of which is substantially symmetric with a right side perspective view.

Fig. 6 front side plan view thereof of a preferred embodiment showing the "V" shaped tip and tip holding shaft.

Fig. 7 is a bottom side plan view thereof of a preferred embodiment showing the rounded edge of the "V" shaped tip and tip holding shaft.

DETAILED DESCRIPTION

Referring now to the drawings, there is shown in FIGS. **1 - 7** a preferred embodiment of a device for radial optic neurotomy **10** having a blade **12** with a sharp edge **22** on a first leg **20** and a dulled edge **28** on a second leg **26** and a depth gauge **30** placed distally from a point **16** of said blade **12**. The device for radial optic neurotomy **10** is particularly adapted to relieve the aforesaid

compartment syndrome during the radial optic neurotomy, (RON) procedure with a minimal risk of hemorrhage.

The present art device for radial optic neurotomy **10** first comprises a substantially asymmetrical "V" shaped tip **14** having a distal point **16**, the base or point **16** of said "V" substantially representing the distal end of the present device. In the preferred embodiment, the top or broad portion **18** of said "V" shaped tip is attached with a tip holding shaft **36** having a proximally attached handle **38**. Said asymmetrical "V" shaped tip comprises a first leg **20** of said "V" having the single sharp edge **22** and a second leg **26** of said "V" opposite said first leg **20** comprising a burnished, dulled, or rounded edge **28**. In a preferred embodiment, said first leg **20** represented by said first single sharp edge **22** is angled approximately 12 degrees from the central axis **37** of said tip holding shaft **36**. Also in a preferred embodiment, said second leg **26** represented by said dulled or rounded edge **28** is angled approximately 10 degrees from the central axis **37** of said tip holding shaft **36**, said angle rotationally opposite said first leg **20**. Alternative embodiments may vary the aforementioned angles considerably without departing from the scope and spirit of the present invention. In the preferred embodiment, the second leg **26** deviates from said 10 degrees as it approaches the base or point **16** of said "V"(i.e. distal end), thereby forming an angle of approximately 30 degrees relative to the central shaft axis **37**. This deviation further places said second leg **26** or dulled edge **28** slightly across the central shaft axis **37** and toward the first leg **20** or sharpened edge **22**, thereby shifting the distal point **16** across the central shaft axis **37** toward said first leg **20** or sharp edge **22**. The aforementioned deviation further ensures that the device **10** and the distal point **16** shall only cut on one side, i.e. the first leg **20** or sharp edge **22**, when inserted near said optic nerve head. The aforesaid 30 degree deviation may be varied considerably without departing from the scope of the present invention provided that the aforementioned benefits are maintained. Alternative embodiments may provide said dulled second leg edge **28** without shifting said second leg **26** across the central shaft axis **37**.

In the preferred embodiment, the sharpened edge **22** is formed from a substantially linear taper plane **24** positioned from a line substantially parallel with said central axis **37** toward the first leg **20** of said "V" **14**. Alternative embodiments may provide said first leg **20** sharpened edge **22** without the aforesaid taper **24**, provided said first leg **20** sharpened edge maintains the aforesaid cutting

characteristics.

In the preferred embodiment, the tip holding shaft **36** is slightly smaller in diameter or width than the top or broad portion of said "V" shaped tip **14**. This configuration requires that the tip attachment with said tip holding shaft **36** transitionally taper **40** to the shaft **36** dimensions. In the preferred embodiment, this transitional taper **40** does not contain a sharpened edge. Alternative embodiments may eliminate said transitional taper **40** or place a sharpened edge on the first leg **20** side of said transitional taper **40**. The second leg **26** side of said transitional taper **40** further maintains the dulled or rounded edge **28** to avoid cutting action on the second leg **26** side.

The preferred embodiment further places a laser mark **34** onto both broad **18** sides of said "V" shaped tip **14** transitional taper **40** area to function as a depth gauge **30**. Again in the preferred embodiment, said laser mark **34** is in the form of a line **32** which is substantially perpendicular with the central shaft axis **37**. Alternative embodiments may place on or more of said marks **34** at any location which would indicate the proper depth of penetration during surgical use or place multiple marks to accommodate varying pathology and/or surgical nuances. Alternative embodiments may further utilize said mark **34** as a partial line or other mark form which is scribed or marked in a fashion other than laser marking or which is positioned in a fashion which is not perpendicular with the central shaft axis or which is located onto only one side.

In one form of the preferred embodiment, the first leg **20** or sharpened edge **22** is approximately .090 inches, the laser mark **34** is positioned proximally from the distal point approximately .108 inches or 2.7 millimeters, the broad portion **18** of said "V" shaped tip **14** is approximately .0465 inches wide at its widest portion, the tip holding shaft **36** is approximately .033 inches in diameter, and the distal point **16** is shifted across the central shaft axis **37** toward said first leg **20** or sharp edge **22** by .003 inches. The aforesaid dimensions are given for enablement purposes only and do not singularly represent the preferred embodiment. Alternative embodiments may vary the aforesaid dimensions considerably provided the first leg **20** sharpened edge **22** and second leg **26** dulled edge **28** characteristics are maintained.

As aforesaid, a handle or grip **38** attaches with said central shaft **36** opposite said "V" shaped tip **14** and proximal to the user. Preferably said handle or grip **38** is cylindrical in form, but may take many forms or shapes which allow a surgeon to easily utilize the device. The present art device is

claimed as the tip**14** in conjunction with the attached shaft **36** and as a further embodiment, the tip **14** with attached shaft **36** and handle or grip **38**.

During utilization of the radial optic neurotomy device **10**, the surgeon inserts the asymmetrical "V" shaped tip **14** radial to the optic nerve head and advances said tip **14** a specified distance thereby relieving the compartment syndrome and relaxing the cribiform plate, scleral ring, and adjacent sclera. In order to minimize hemorrhage and other complications, the first leg **20** sharp edge **22** is positioned whereby a radial incision proceeds nasally to or away from the optic nerve head and the second leg **26** dulled edge **28** proceeds alongside or near the optic nerve head, central retinal artery, or central retinal vein without incision promotion, thereby allowing atraumatic passage of the device **10**.

Those skilled in the art will appreciate that a radial optic neurotomy (RON) knife utilized for surgical decompression of central retinal vein occlusion (CRVO) has been shown and described. That said present art is capable of providing a radial incision on the nasal aspect of the optic nerve head, a relaxing incision to the scleral ring and cribiform plate by means of an extremely sharp edge on the nasal portion of the device. The device further provides an atraumatic passage of the knife past the central retinal vessels due to a burnished and dulled or rounded medial edge. The present art may further be utilized in general retinovascular ophthalmic surgery.

Having described the invention in detail, those skilled in the art will appreciate that modifications may be made of the invention without departing from its spirit. Therefore, it is not intended that the scope of the invention be limited to the specific embodiments illustrated and described. Rather it is intended that the scope of this invention be determined by the appended claims and their equivalents.